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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,391	04/14/2004	Joan D. Leonard	12780/103	8469

26646 7590 06/01/2005

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,391	LEONARD ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/14/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction/Election

1. The restriction/election mailed May 25, 2005 is vacated because of the preliminary amendment filed March 7, 2005. The Office apologizes for this oversight. A first action on the merits is set forth below:

Priority

2. The application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). The instant application is not granted priority to provisional application 60/164, 286, filed November 8, 1999 for the reasons stated above. However, the instant application is granted priority to U.S. Patent Application 09/708,352 filed November 8, 2000.

Claim Objections

3. Claim 23 and 28 are objected to because of the following informality: "*Hemophilus*" should be changed to *Haemophilus*". Correction is required.

4. Applicant is advised that should claims 21-25 be found allowable, claims 26-30 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claim 22 lacks antecedent basis in claim 21. Claim 21 recites "... at least two inactivated *Mycoplasma bovis* biotypes and inactivated *Mycoplasma alkalescens...*". Claim 22 recites "the vaccine of claim 21 further comprising antigenic material of other viruses or microorganisms known to be bovine pathogens". Since 22 depends claim 21, it should noted that *M. bovis* and *M. alkalescens* are not viruses. Therefore, claim 22 lacks antecedent basis.

Claim Rejection - 35 USC 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 21-30 are rejected under 35 U.S.C. 103(a) as unpatentable over Stott et al *(The Veterinary Record, October 10, 1987)* in view of Poumarat et al, *(Veterinary Microbiology, Volume 40, 1994, p. 305-321) in view of* Gourlay et al (*Res Vet Sci., September 1979, 27; 233-7)* and further in view of Chima et al, *(Veterinary Microbiology Vol. 5, pp. 113-122, (1980).*

Claims 21-30 are drawn to a vaccine which is protective in bovine species against respiratory disease resulting from *Mycoplasma* infection comprising (a) at least two inactivated *Mycoplasma bovis* biotypes; (b) inactivated *Mycoplasma alkalescens*; (c) an adjuvant; and (d) a pharmaceutically acceptable excipient.

Stott et al disclose a quadrivalent vaccine containing the killed antigens of respiratory syncytial virus, parainfluenza virus type 3, *Mycoplasma bovis* and *Mycoplasma dispar* (see the Abstract). Stott et al disclose that the vaccine were emulsified using Freund's incomplete adjuvant and formulated with Tween 80 and merthiolate (page 343).

Stott et al do not teach at least two different *M. bovis* biotypes *Mycoplasma bovis.*

Poumarat et al teach *Mycoplasma bovis* of different biotypes. Poumarat et al teach that Restriction endonuclease analysis (REA) with three enzymes *Sma*I, *Pst*I, and *Bam*I which were used to identify 13 different genomic groups (i.e. biotypes) among 37 *Mycoplasma bovis* strains (see the Abstract). Poumarat et al disclose 37 bovis strains studied gave five different electrophoretic patterns with BamHI, four with *Sam*I and five with *Pst*I (figure 1). Poumarat et al further disclose that based on the combination of the different electrophoretic profiles obtained with the three enzymes, the 37 strains could be classified in 13 genomic groups (table 2).

Stott et al and Poumarat et al as combined above do not teach *Mycoplasma alkalescens.*

Gourlay et al teach that *Mycoplasma alkalescens* is associated with the respiratory tract of bovine (see the Abstract). Gourlay et al teach that *Mycoplasma alkalescens* can colonize the lower respiratory tract but does not produce visible pneumonia (see the Abstract). Therefore, one of ordinary skill in the art could reasonably conclude that *M. alkalescens* is a secondary agent associated with respiratory infections in bovine.

Stott et al, Poumarat et al, Gourlay et al as combined above do not teach inactivated *Mycoplasma alkalescens*.

However, Chima et al teach that inactivated (formalinized) vaccines have advantages over live vaccines because vaccines comprising live organisms have been shown to result in residual infections three to four months after vaccination (page 120). Additionally, vaccines comprising live organisms have the potential of reversion to full virulence and have been shown to provoke local reaction at the site of inoculation (page 121). Therefore, one of ordinary skill in the art could reasonably conclude that using inactivated components such as inactivated *M. alkalescens* in vaccine compositions is safer than using live organisms.

Therefore, it would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add inactivated *Mycoplasma alkalescens* and inactivated *Mycoplasma bovis* isolates of different biotypes to the vaccine composition as taught by Scott et al because Poumarat et al teach that there is a marked intraspecies genomic heterogeneity among isolates of *Mycoplasma bovis* collected from different geographic origins and that antigenic variability must be taken into account in developing diagnostic and vaccination strategies (page 319) and Stott et al teach that a multicomponent vaccine comprising inactivated components would protect against the important primary pathogens of respiratory disease as well as protecting against secondary agents of respiratory disease (page 342). It would be expected that a vaccine composition comprising inactivated *M. bovis* strains of multiple biotypes,

inactivated *Mycoplasma alkalescens*, a pharmaceutically acceptable excipient and a suitable adjuvant would be effect against respiratory infections in cattle because Stott et al teach that major outbreaks of respiratory disease in cattle suggest that other agents are involved in the disease complex. Therefore, it would be advantageous to included additional antigens in vaccines (page 346).

Status of Claims

7. No claims allowed.

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
May 18, 2005

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